

M E M O R A N D U M

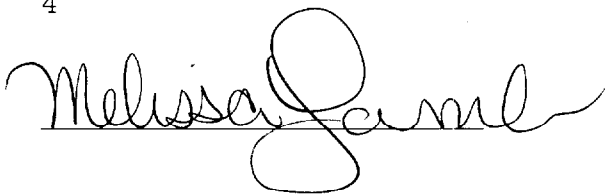
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

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Date: February 24, 2000
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: Guidance for ANDAs: Blend Uniformity Analysis

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Guidance for ANDAs: Blend Uniformity Analysis
Presented for: Generic Trade Associations Meeting
Date Presented: 2/24/00
Presented by: Frank O. Holcombe
Number of Pages: 4

A handwritten signature in cursive script, reading "Melissa Lamb". The signature is written in dark ink and is positioned below the typed name "Melissa Lamb" in the distribution list.

Attachment

90S-0308

M666

Office of Generic Drugs
Generic Trade Associations Meeting
February 24, 2000

Guidance for
ANDAs: Blend Uniformity Analysis

Frank O. Holcombe, Jr.
Associate Director for Chemistry
Office of Generic Drugs

Issues -

- **Good Manufacturing Practices**
- **Deletion of Testing**
- **Sampling/Samples**
- **Single vs Multiple Tier Testing**

ISSUES -

Product Quality Research Institute

PQRI/FDA Collaboration

Blend Uniformity Working Group

Highest Priority Topic

Issues -

CLARIFICATION -

- **Scope**
- **Product Criteria**
- **Multiple Blending Steps**
- **Different Product Assay Criteria**